REMARKS

In response to the office action mailed January 5, 2010 ("Office Action"), the specification and claims 1, 14 and 15 are amended. Claims 1-8, 10 and 12-15 are presented for further examination.

Initially, Applicants would like to thank the Examiner for the telephone interview with their counsel held on April 13, 2010. During the interview, the patentability of independent claim 1 was discussed in view of the prior art cited in the Office Action. A partial summary of the interview is provided in the Interview Summary issued on April 19, 2010. Other points discussed during the interview are included in the discussion below.

Claims 1-8, 10 and 12-15 were rejected under 35 U.S.C § 102(b) as anticipated by, or under 35 U.S.C § 103(a) as obvious from, Shimagaki et al., U.S. Patent No. 6,103,117 ("Shimagaki").

Independent claim 1 is discussed first. Claim 1, as amended, recites a separation membrane that has at least the following features:

> (a) the separation membrane is made mainly of a polysulfone-based polymer and polyvinyl pyrrolidone, where a ratio [D]/[C] between the polyvinyl pyrrolidone content [D] in the uppermost layer of a surface on non-blood contacting side and the polyvinyl pyrrolidone content [C] in the uppermost layer of a surface on blood contacting side is 1.1 or higher; and
> (b) when bovine blood at a temperature of 37°C having hematocrit value of 30% and containing 6 to 7 g/dl of total proteins and sodium citrate is flowed through a module containing the separation membrane at a flow rate of 200 ml/min. and a filtration rate of 20 ml/min.:
>
> (i) a sieving coefficient of albumin [A] becomes not less than 0.01 and not more than 0.1 after 15 minutes; and
>
> (ii) a sieving coefficient of albumin [B] becomes not less than 0.005 and less than 0.04 after 2 hours.

According to the specification, the membrane recited in claim 1 can effectively remove α1-microglobulin (which has a molecular weight of 33,000 and is a uremic toxin) from the blood flowing through it, while suppressing the leakage of albumin (which has a molecular weight of 66,000 and is a useful protein) in the blood. *See, e.g.*, paragraphs [0034]-[0036].

The Office does not dispute that Shimagaki does not explicitly disclose either feature (a) or feature (b), but argues that Shimagaki inherently discloses a membrane having both features. Specifically, the Office asserts that

> the PVP content along with the differential extraction between the inner and outer surface by adjusting the core fluid and the coagulation bath/wash solutions would inherently achieve the PVP ratio between the two surfaces as claimed. Applicants has not provided any evidence to show that the Reference membrane would not meet this condition.

See the Office Action, page 4, 2nd last paragraph; emphasis added. Applicants respectfully disagree. The Office is reminded that, "[t]he fact that a certain result of characteristic **may** occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." *See* MPEP 2112 IV; emphasis original. To reply upon the theory of inherency, "the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic **necessarily** flows from the teachings of the applied prior art." *Id*; emphasis original. Here, however, the Office has provided no such showing. Indeed, given Shimagaki's lack of any meaningful teaching with respect to the PVP content in the inner and outer surface of its membrane and its membrane's ability to remove α1-microglobulin, one skilled in the art would not conclude that Shimagaki discloses a membrane that **necessarily** has both features (a) and (b) recited in claim 1. Thus, the Office has not met its burden in establishing that Shimagaki inherently discloses the membrane recited claim 1.

In addition, the membranes prepared by Examples 4-7 in Shimagaki, which are believed to be the closest examples to the membrane recited in claim 1, have been reproduced. *See* paragraph 3 in the declaration from Mr. Kimihiro Mabuchi ("the Declaration"), a copy of which is attached as Exhibit A. Specifically, as shown in Table 1 in the Declaration, the membranes prepared by Examples 4-7 in Shimagaki have an albumin sieving coefficient between 0.005 and 0.04 after flowing blood through them for 1 hour and might satisfy feature (b)(ii) recited in claim 1 (which requires an albumin sieving coefficient between not less than 0.005 and less than 0.04 after flowing blood through a membrane for 2 hours). *See* paragraph 4 in the Declaration. On the other hand, the membranes prepared by the Examples in Shimagaki other than Examples 4-7

have an albumin sieving coefficient less than 0.005 after flowing blood through them for 1 hour and, therefore, cannot satisfy feature (b)(ii) recited in claim 1. *Id.*

However, even though the membranes prepared by Examples 4-7 in Shimagaki might have an albumin sieving coefficient that falls within the range in feature (b)(ii) recited in claim 1, they do not possess a [D]/[C] ratio of 1.1 or higher, as recited in feature (a) of claim 1. *See* paragraph 6 in the Declaration. Specifically, Table 2 in the Declaration shows that the membranes prepared by Examples 4-7 in Shimagaki have a [D]/[C] ratio ranging from 0.9-1.0, which is less than the [D]/[C] ratio of 1.1 or higher recited in feature (a) of claim 1. Given that the membranes prepared by the closest examples described in Shimagaki still do not meet both features (a) and (b) recited in claim 1, Applicants submit that Shimagaki does not inherently anticipate claim 1.

Further, there is nothing in Shimagaki that would have prompted one skilled in the art to modify the membranes described therein to provide the membrane recited in claim 1. Nor has the Examiner provided any reason to do so other than improper hindsight. Thus, Shimagaki also does not render claim 1 obvious.

During the interview held on April 13, 2010, the Examiner asserted that, even if Applicants provide evidence showing that certain examples described in Shimagaki do not inherently disclose the membrane recited in claim 1, that evidence may not be sufficient to overcome this rejection since Applicants have not shown whether other portions in Shimagaki inherently disclose such a membrane. Applicants have submitted evidence demonstrating that the membranes described in Shimagaki that are believed to be the closest to that recited in claim 1 still do not possess the features of the claimed membrane. If the Examiner were to maintain the rejection of claim 1 in view of Shimagaki, Applicants request that the Examiner provide evidence showing which portion of Shimagaki inherently discloses or renders obvious the membrane recited in claim 1 and explain how the membranes disclosed in that portion of Shimagaki satisfy or render obvious the features recited in this claim.

In sum, claim 1 is not anticipated or rendered obvious by Shimagaki. As claims 2-8, 10 and 12-15 depend from claim 1, they also are not anticipated or rendered obvious by Shimagaki.

Applicants submit that this application is now in condition for allowance.

Any circumstance in which Applicants have: (a) addressed certain comments of the Examiner does not mean that Applicants concede other comments of the Examiner; (b) made arguments for the patentability of some claims does not mean that there are not other good reasons for the patentability of those claims and other claims; or (c) amended or canceled a claim does not mean that Applicants concede any of the Examiner's positions with respect to that claim or other claims.

The $1,110.00 fee for the Petition for Three-Month Extension of Time is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization.

Please apply any other charges to deposit account 06-1050, referencing Attorney's Docket No. 19461-0005US1.

Respectfully submitted,

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